OCT 1 0 2001

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510(k)
Summary
Duracon® PS Lipped Tibial Insert

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:

Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677

Contact Person:

Mary-Catherine Dillon
Regulatory Affairs Specialist
and
Susan Krasny, PhD
Director, Regulatory Affairs

Date of Summary Preparation: July 10, 2001

Device Identification

Proprietary Name: Duracon® PS Lipped Tibial Insert

Common Name: Knee Prosthesis

Classification Name and Reference: Knee Joint, Patellofemorotibial, Polymer/Metal/Polymer, Semi-Constrained, Cemented Prosthesis
21 CFR '888.3560

Predicate Device Identification

The Duracon® PS Lipped Tibial Bearing Inserts are substantially equivalent to the Duracon® Stabilized Tibial Inserts cleared via K932070 and K936292.

Device Description

The Duracon® PS Lipped tibial inserts share the same critical design features as the predicate Duracon® Stabilized tibial inserts. They both have the same snap-fit locking

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mechanism, augmented by a locking screw, for mating with the current Duracon® tibial baseplates (K915512). The subject Duracon inserts are intended to be used with current Duracon® femoral and patellar components. The subject inserts will be available in the same range of sizes and thicknesses and are manufactured from the same materials as the current Duracon® Stabilized inserts.

The subject inserts have an anterior/posterior (A/P) lipped feature to enhance femoral/tibial implant anterior stability in full extension. In addition, the subject inserts incorporate a patellar cut-out feature to improve patellar tracking.

Intended Use

The intended use of the Duracon® PS Lipped tibial inserts is identical to that of the predicate Duracon® Stabilized tibial bearing inserts. As with the predicate inserts, the modified inserts are single use devices for use as part of a total knee system in primary or revision cemented total knee arthroplasty. These inserts are intended to be used in cases where there is destruction of the joint surfaces with or without bone deformity, where the cruciate ligaments are inadequate, not present, or cannot be preserved during the operative procedure, especially when anterior-posterior stability is impaired due to absence of the patella. The collateral ligaments may or may not be used for revision of a failed prosthesis.

Indications

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis,
- Rheumatoid arthritis,
- Correction of functional deformity,
- Revision procedures where other treatments or devices have failed,

- Post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy; and,
- Irreparable fracture of the knee

Contraindications

Absolute contraindications include:

- Overt infection,
- Distant foci of infections (which may cause hematogenous spread to the implant site),
- Rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram,
- Skeletally immature patients
- Cases where there is poor bone stock which would make the procedure unjustifiable,

Conditions presenting an increased risk of failure include:

- Uncooperative patient or patient with neurological disorders who is incapable of following instructions,
- Osteoporosis,
- Metabolic disorders which may impair bone formation,
- Osteomalacia, and
- Previous arthrodesis

Performance Data

Mechanical testing has been performed to demonstrate the substantial equivalence of the subject inserts to the predicate inserts.

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Statement of Technological Comparison

The fundamental scientific technology of the current Duracon® PS Lipped tibial inserts has not changed with regard to the modified inserts. The modified inserts employ the same basic design concepts, the same materials, and the same manufacturing methods.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2001

Ms. Mary-Catherine Dillon
Regulatory Affairs
Howmedica Osteonics Corp.
59 Route 17
Allendale, New Jersey 07401-1677

Re: K012172
Trade Name: Duracon® Posteriorly Stabilized Lipped Tibial Insert
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: June 22, 2001
Received: July 12, 2001

Dear Ms. Dillon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N Milhern

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012172

Device Name: Duracon® Posteriorly Stabilized Lipped Tibial Insert

The Duracon® Posteriorly Stabilizer (PS) Lipped Tibial Inserts are intended to be used with legally marketed Duracon® tibial baseplates and wedges, femoral components, and patellar components as part of a total knee system in primary or revision cemented total knee arthroplasty. These inserts are intended to be used in cases where there is destruction of the joint surfaces with or without bone deformity, where the cruciate ligaments are inadequate, not present, or cannot be preserved during the operative procedure, especially when anterior-posterior stability is impaired due to absence of the patella. The collateral ligaments may or may not be used for revision of a failed prosthesis.

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the Counter Use (Per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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